

K120166

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**510(K) SUMMARY**

[as required by 807.92(c)]

A. 510k Number:

B. Applicant:

Company name: PATS CORP

Address: 4568 W. 1st Street, Suite 104 Los Angeles, CA 90004, USA

Contact person: Mr Daniel Nam

Phone: 213-626-1544 FAX: 213-626-1548

C. Proprietary and Established Names: WON INDUSTRY CO LTD

Address: 22-5, Daeya-dong, Siheung-si, Gyeonggi-do, Korea

D. Regulatory Information

1. Classification Name: Massager, Powered Inflatable Tube
2. Common / Usual Name: Powered Inflatable Tube Massager
3. Proprietary Name: Compressible Limb Therapy System WIC-2008S
4. Classification / Product Code: Class II / IRP (21 CFR 890.5650)

E. Intended Use

WIC-2008S is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as :  
Primary lymphedema, Edema following trauma and sport injuries,  
Postimmobilization edema, Venous insufficiencies, Lymphedema.

F. Device Description

WIC-2008S is used with four chamber garments for full leg, and period has its own variable duration, pressure, cycle time and gradient setting. Power unit features visual operation status and fault indicators.

G. Substantial Equivalence Information

Predicate Device

- 510(k) number: K102319

- Name: Compressible Limb and Circulation Therapy Systems  
(WIC-2008)

- Classification: 2

1. Comparison with predicate

Compressible Limb Therapy System WIC-2008S has substantial equivalent intended use as the-market-cleared Compressible Limb Therapy System WIC-2008 and has substantial equivalent technological and performance characteristics.

After analyzing both bench as well as laboratory testing to applicable standards, it is the conclusion of WON INDUSTRY Co Ltd. that Compressible Limb Therapy System WIC-2008S is as safe and effective as the predicate devices, has few technological differences, but there are no new indications for use and without raising any new safety and/or effectiveness concerns. Consequently, it is clear that it substantially equivalent to the predicate devices

H. Performance Characteristics (If/when applicable)

WIC-2008 has conducted and applied by standard of

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- IEC 980:2008, Graphical symbols for use in the labeling of medical devices
- IEC1041:2008, Information supplied by the manufacturer with medical devices
- ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14155-1:2003, Clinical investigation of medical devices for human subjects - Part 1: General requirements
- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988/A1:91/A2:95)
- IEC 60601-2-10, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- IEC 60601-1-2, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

MAY 14 2012

Won Industrial Co.  
% PATS Corporation  
Mr. Daniel Nam  
4568 West 1<sup>st</sup> Street, Suite 104  
Los Angeles, California 90004

Re: K120166  
Trade/Device Name: Compressible Limb Therapy System WIC-2008S  
Regulation Number: 21 CFR 890.5650  
Regulation Name: Powered inflatable tube massager  
Regulatory Class: Class II  
Product Code: IRP  
Dated: April 27, 2012  
Received: May 3, 2012

Dear Mr. Nam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

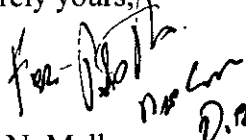
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a date "D.12" written below it.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## Indications for Use

510(k) Number (if known):

Device Name: Compressible limb therapy system WIC-2008S


Indications for Use: WIC-2008S is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as : Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

Prescription Use   X   AND/OR Over-The-Counter Use        (Part 21 CFR 801  
Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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